Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of hemodynamic effects of biventricular versus left ventricular only pacing in patients receiving cardiac resynchronization therapy: a before-after clinical trial

Protocol summary

Summary

Objectives: To assess hemodynamic effects of biventricular versus left ventricular only pacing in patients receiving Cardiac Resynchronization Therapy Design: A before-after clinical trial Setting and conduct: All patients with CRT who refer to electrophysiological clinic of Ekbatan hospital for programing in 2012 Participants including major eligibility criteria: All patients with CRT will be included unless they have not responded to CRT. Intervention: In intervention group, the CRT pacemaker will be set for left ventricular only pacing for three month. In control group, the CRT pacemaker will be left as biventricular pacing for three months. Main outcome measures: The hemodynamic status of the patients will be assess at baseline and three months later as follows: (a) Velocity Time Integral (VTI) of aortic valve per cm; (b) Left Ventricular End Diastolic Volume (LVEDV) of aortic valve per ml; (c) Left Ventricular End Systolic Volume (LVESV) of aortic valve per ml; (d) Left Ventricular Ejection Fraction (LVEF) of aortic valve per percent

General information

Acronym

CRT: Cardiac Resynchronization Therapy

IRCT registration information

IRCT registration number: **IRCT201203169014N7**
Registration date: **2012-07-02, 1391/04/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-07-02, 1391/04/12

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-07-21, 1392/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic effects of biventricular versus left ventricular only pacing in patients receiving cardiac resynchronization therapy: a before-after clinical trial

Public title

Comparison of hemodynamic effects of biventricular versus left ventricular only pacing in patients receiving Cardiac Resynchronization Therapy (CRT)

Purpose

Treatment

Inclusion/Exclusion criteria

All patients with CRT will be included unless they have not responded to CRT.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local Human Subject Review board of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Approval date

2012-06-26, 1391/04/06

Ethics committee reference number

D/P/16/35/9/1114

Health conditions studied

1

Description of health condition studied

Cadiac Resynchronization Therapy (CRT)

ICD-10 code

I49

ICD-10 code description

Other cardiac arrhythmias

Primary outcomes

1

Description

Four variables will be considered for assessing hemodynamic status of the patientsat baseline, three and six month later including: (a) Velocity Time Integral (VTI) of aortic valve per cm; (b) Left Ventricular End Diastolic Voliume (LVEDV) of aortic valve per mL/m2; (c) Left Ventricular End Systolic Voliume (LVESV) of aortic valve per mL/m2; (d) Left Ventricular Ejection Fraction (LVEF) of aortic valve per percent.

Timepoint

3 months

Method of measurement

Ecocardiography

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group, the CRT pacemaker will be set for left ventricular only pacing for three months

Category

Treatment - Devices

2

Description

In control group, the CRT pacemaker will be left as biventricular pacing for three months

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ekbatan Hospital

Full name of responsible person

Dr Babak Faghfurian

Street address

Department of Cardiology, School of Medicine

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person
Dr Ahmad Tavilani
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Hamadan
Grant name
از محل يك درصد بودجه طرح‌هاي تحقيقاتي دانشگاه
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vic-Chancellor of Research and Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty